



## DECLARATION OF CONFORMITY CERTIFICATE

**MANUFACTURER:** Hyaltech Ltd.  
Starlaw Business Park  
Livingston, EH54 8SF,  
United Kingdom

**PRODUCT:** **Fermathron**  
Synovial Viscosupplement device  
Product number: 030001  
Biomet Reference number: 236380 - INT  
GMDN code: P44757

**CLASSIFICATION:** Class III; Annex IX, Rule 8.  
**CONFORMITY ASSESSMENT ROUTE:** Annex II

We herewith declare that the above mentioned product meets the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer.

**STANDARDS APPLIED:** List of standards for which documented evidence  
for compliance can be provided

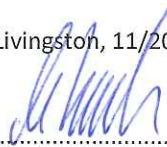
**NOTIFIED BODY:** DEKRA Certification B.V.  
Meander 1051  
6825 MJ Arnhem  
P.O. Box 5185  
6802 ED Arnhem  
The Netherlands  
Notified body number: 0344

**EC CERTIFICATE:** 2011354CE06  
**DESIGN EXAMINATION CERTIFICATE:** 2011354DE04

**START OF CE MARKING:** Originally CE marked on 08 September 1999 by MDC  
**FIRST CE BATCH:** 3530AA manufactured December 2005

**PLACE, DATE OF ISSUE:** Livingston, 11/2016

**SIGNATURE:**

 25/11/2016  
Michael Haisch  
Managing Director  
For and on behalf of Hyaltech Ltd.

**SIGNATURE:**

 25 Nov 2016  
Carolyn Melvin  
Regulatory Affairs Supervisor  
For and on behalf of Hyaltech Ltd.